K053270

VersaMed Medical Systems Inc.
2 Blue Hill Plaza Bldg. 2
Pearl River, NY 10965
USA

Non-Confidential Summary of Safety and Effectiveness

Summary of Safety and Effectiveness

Submitter's Name:

VersaMed Medical System Inc.

Contact Person:

Mr. Jerry Korten
Tel: 845 770 8240
Fax: 845 770 8250

Trade Name:

iVent™ 201 Portable Ventilator

Classification Name:

Anesthesiology

Classification:

CBK, DQA, NOU.

Predicate Devices:

The iVent™ 201 Portable Ventilator is substantially equivalent to:

- iVent™ cleared under K052554
- TBIRD VELA cleared under K032451

Performance Standards:

No performance standards have been established for such devices under Sections 514 of the Federal Food, Drug, and Cosmetic Act. However, the ***iVent™ 201*** portable ventilator complies with the following voluntary standards:
ASTM F 1100-90
ASTM F 1246-91
MIL-STD-810E
ISO 10651-1/2/3
IEC 60601-1
IEC 60601-2-12
IEC 60601-1-2
CAN/CSA-C22.2 No.601.1
ISO 9919
EN 865 (section 6)

The non clinical testing results provides assurance that the device meets it's specifications and is safe and effective for its intended use.

Device Description:

The iVent201 is a compact, portable, fully featured, microprocessor-controlled ventilator offering the versatility and capability of larger and costlier ventilators. A turbine-powered air source and a rechargeable internal battery provide freedom from wall air and power outlets. An intuitive turn-and-click control knob, quick-choice pushbuttons, and a bright, well-organized, easy-to-read screen allow rapid control and continuous real-time monitoring of patient ventilation. Alarm settings are fully adjustable. Optional Waveform and Diagnostic Software package displays pressure and flow waveform data, loops, trends, and logged totals in a full array of time slices and presentation modes.

Description of Non- invasive Pulse Oximeter: The Non-invasive Pulse Oximeter connects to sensors and provides oxygen saturation, pulse rate, pulse waveform, and

other output information via a serial digital interface. The iVent 201 systems provide isolated DC power.

The Non-invasive Pulse Oximeter board is mounted internal to the iVent 201 unit and is part of the electronic configuration of the unit. Connection of the Pulse Oximeter accessories is via a connector on the back panel of the unit.

Description of remote Alarm Adaptor: The adapter connects between a Remote Alarm outlet on the iVent 201 Ventilator and the Central Remote Alarm unit of the Hospital. The adapter consists of a relay circuit, which meets activating requirements of the Central Remote Alarm unit.The iVent 201 Ventilator with Remote Alarm Adapter will activate the Central Remote Alarm unit for any major or medium priority alarm event that occurs on the unit.

Intended use:

The iVent™ 201 is a portable, computer controlled, electrically powered ventilator intended to provide continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation. Specifically, the ventilator is applicable for adult and pediatric patients weighing at least 10 kg (22 lb.), who require the following general modes of ventilatory support, as prescribed by an attending physician:
Assist/Control (Pressure Controlled or Volume Controlled)
SIMV (Pressure Controlled or Volume Controlled)
CPAP/PSV

The iVent™ 201 ventilator with Non-invasive Pulse Oximeter is suitable for intera-hospital use, home and alternate-site use, transport and emergency use. The Non-invasive Pulse Oximeter is intended for non-invasive monitoring of oxygen saturation and pulse rate.

The i™ 201 ventilator is a restricted medical device intended for use by qualified, trained personnel under the direction of a physician and within the technical specification limits.

Substantial Equivalence:

The iVent™ 201 portable ventilator is viewed as substantially equivalent to the following predicate devices;

- iVent™ cleared under K052554
- TBIRD VELA cleared under K032451

The iVent 201 –portable ventilator in this submittal is the same device as the cleared device under K052554 except for the modifications associated with this submittal:

- The incorporation of the ability to deliver 7LPM oxygen gas flow to an external nebulizer that is gated to the occurrence of a breath into the iVent 201 device.
- The incorporation of the ability to measure static compliance using inspiratory hold and the ability to measure auto PEEP using end expiratory hold into the iVent 201 device.

There are no significant differences between the iVent™ 201 portable ventilator in this submittal and the predicate device under K052554 that affect the safety or effectiveness of the intended device as compared to the predicate devices. The iVent 201 portable ventilator is viewed as substantially equivalent to the predicate device since they:

1. Have the same intended use:
   1.1 The iVent™ 201 is a portable, computer controlled, electrically powered ventilator intended to provide continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation.

2. Have the same environment for use:
   2.1 intra-hospital use, home and alternate-site use, transport and emergency use.

3. Have the same patient popultion :
   3.1 this system can be used with adult and pediatric patients weighing at least 10 kg (22 lb.).

4. Are similar in design

5. Employ the same technology

6. Are made of identical materials

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 27 2006

Mr. Jerry Korten
VersaMed Medical Systems, Incorporated
CEO & President
2 Blue Hill Plaza Building 2
Pearl River, New York 10965

Re: K053270
Trade/Device Name: iVent™ 201 Portable Ventilator
Regulation Number: 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: January 5, 2006
Received: January 6, 2006

Dear Mr. Korten:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K053270

Device Name: **iVent™ 201 Portable Ventilator**

Indications for Use:

The ***iVent™ 201*** is a portable, computer controlled, electrically powered ventilator intended to provide continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation. Specifically, the ventilator is applicable for adult and pediatric patients weighing at least 10 kg (22 lb.), who require the following general modes of ventilatory support, as prescribed by an attending physician:

- Assist/Control (Pressure Controlled or Volume Controlled)
- SIMV (Pressure Controlled or Volume Controlled)
- CPAP/PSV

The ***iVent™ 201*** ventilator with Non-invasive Pulse Oximeter is suitable for intra-hospital use, home and alternate-site use, transport and emergency use. The Non-invasive Pulse Oximeter is intended for non-invasive monitoring of oxygen saturation and pulse rate.

The ***iVent™ 201*** ventilator is a restricted medical device intended for use by qualified, trained personnel under the direction of a physician and within the technical specification limits.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K053270